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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,005	07/03/2003	Juergen Andrew Kortcnbach	06530.0170-05	3367

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/612,005

Examiner

Diane Yabut

Applicant(s)

KORTENBACH, JUERGEN
ANDREW

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 110-137 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 110-137 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on
13 October 2006.

Examiner acknowledges the corrections made to the abstract and the
amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the
United States before the invention thereof by the applicant for patent, or on an international application
by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this
title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act
of 1999 (AIPA) and the Intellectual Property and High Technology Technical
Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting
directly or indirectly from an international application filed before November 29, 2000.
Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior
to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 110, 120-122, 124, 129, 130, 135, and 137 are rejected under 35
U.S.C. 102(e) as being anticipated by **Bolanos** (U.S. Patent No. **5,897,562**).

Claims 110, 129, 130, and 137(new): Bolanos discloses a surgical instrument
comprising an elongated tube **18** having a proximal end for extending outside of the

body and a distal end for positioning proximate multiple tissue layers, a distal member 22 coupled proximate the distal end of the tube and configured to fold a fundus of a stomach toward an esophageal wall or multiple tissue layers together, the distal member including a first member (distal end of 18) having a proximal end coupled to the distal end of the tubular member and a distal end, a second member, or rotatable member, being configured to rotate between a first position in which the free end is located distally of the connected end and a second position in which the connected end is located distally of the free end, and the second member 38 having a connected end and a free end and rotatably coupled to the distal end of the first member, and a grasper 26 configured to grasp at least a portion of the fundus or esophageal wall, wherein the grasper is coupled to one of the elongated tube and the distal member (Figures 1 and 12-13).

Claim 120: Bolanos discloses the at least a portion of the fundus or the esophageal wall grasped by a grasper is a gastroesophageal junction (col. 7, lines 41-59).

Claim 121: Bolanos discloses a method of performing invagination, which comprises providing the surgical instrument of claim 110, inserting the surgical instrument transorally into a stomach, grasping a portion of the fundus or the esophageal wall with the grasper, and folding the fundus toward the esophageal wall with the distal member, while grasping the portion of the fundus or the esophageal wall (Figures 12-13, col. 7, lines 41-59).

Claim 122: Bolanos discloses a grasper 26, which is integrally formed with the distal member (Figure 1).

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Claims 124 and 135: Bolanos discloses applying a fastener 30 with the distal member to secure the fundus to the esophageal wall or multiple tissue layers (col. 7, lines 60-67, col. 8, lines 1-14).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 111-116, 123, 131-134, and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**), as applied to Claims 110, 121, and 129 above, and further in view of **Harrison** (U.S. Patent No. **5,403,326**) and **Huitema** (U.S. Patent No. **5,562,701**).

Claims 111-114, 116, 123, 131-134, and 136: Bolanos discloses the claimed device, including the fastener having a first part and a second part (col. 2, lines 34-36), except for the grasper being located between two members, a first grasping member and a second grasping surface associated with the first grasping surface so as to grasp the at least the portion of the fundus or esophageal wall or the multiple tissue layers therebetween, and the distal member including a stationary (first) member and a rotatable (second) member rotatably coupled to the stationary member.

Harrison teaches a grasper 72 being located between two members, a first grasping member 66 and second grasping surface 66 associated with the first grasping

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surface so as to grasp the at least the portion of the fundus or esophageal wall or the multiple tissue layers therebetween (Figure 8C). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the grasper between two members, as taught by Harrison, to Bolanos since it was known in the art that having a grasper between two grasping members provides more grasping force and effective manipulation of tissue.

Huitema teaches a stationary member **412** and a rotatable member **414** rotatably coupled to the stationary member, the rotatable member rotatably movable with respect to the stationary member between a first position capable of receiving at least a portion of a fundus and the esophageal wall and a second position for folding the fundus of the stomach toward the esophageal wall or for folding multiple tissue layers therebetween (Figure 21 and col. 21, lines 1-11). Huitema teaches that this jaw configuration is desirable when the working area is confined and can be incorporated in instruments with relatively small cross sections (col. 1, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a stationary member and a rotatable member rotatably coupled to the stationary member, as taught by Huitema et al., to Bolanos in order to be used in confined working spaces.

Claim 115: Bolanos discloses the distal member being configured to deploy a fastener **30** to the folded fundus and esophageal wall (col. 7, lines 60-67, col. 8, lines 1-14).

Harrison teaches a fastener having a male member **92,94** and a female member **96**, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members (Figure 8C-8D). It is noted that one of the male member and female members is considered stationary once it grasps the tissue and another of the male and female members can rotate towards the stationary member (angular displacement). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the male and female members, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art to provide secure engagement with tissue to prevent undesirable movement.

Claim 126: Bolanos discloses the claimed device except for rotating at least one of the first and second parts with respect to the other of the first and second parts so as to cause engagement between the male and female members.

Harrison teaches rotating at least one of the first and second parts with respect to the other of the first and second parts so as to cause engagement between the male and female members (Figures 8C and 8D). It would have been obvious to one of ordinary skill in the art at the time of invention to provide rotating at least one of the first and second parts with respect to the other, as taught by Harrison, since it was known in

the art that rotation in the process of applying fastener members facilitates the device maneuvering around tissue and layers of tissue.

6. Claim 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**) and **Harrison** (U.S. Patent No. **5,403,326**), as applied to Claim 117 above, and further in view of **Huitema** (U.S. Patent No. **5,562,701**).

Claim 118: Bolanos and Harrison disclose the claimed device except for one control cable extending from the control member to at least one of the distal member and the grasper through the tube.

Huitema teaches the use of a control cable **440** that is connected to the distal member and extends to the control member (col. 21, lines 20-31). Huitema teaches that the use of control cables are advantageous as tension members and their loop construction is beneficial when using certain brittle cord materials (col. 4, lines 11-35). It would have been obvious to one of ordinary skill to provide a control cable, as taught by Huitema, to Bolanos and Harrison in order to actuate the distal member by using tension and allowing for use of certain materials that are susceptible to brittleness.

7. Claims 119 and 128 rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**), as applied to Claims 110 and 121 above, and further in view of **Stevens et al.** (U.S. Patent No. **5,797,960**).

5. Claims 117 and 125-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**), as applied to Claims 110 and 124 above, and further in view of **Harrison** (U.S. Patent No. **5,403,326**).

Claims 117 and 127: Bolanos discloses the claimed device, including a control member or actuator **14** located or coupled proximate the proximate end of the tube configured to control operation of at least one of the distal member and the grasper **26** (col. 5, lines 43-67), except for being used for engagement between male and female members of a fastener.

Harrison teaches a grasper **72** being used for engagement between male and female members of a fastener (col. 8, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a control member being used for engagement between male and female members of a fastener, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art to provide secure engagement with tissue to prevent undesirable movement.

Claims 125-126: Bolanos discloses the claimed device except for a fastener having a male member and a female member, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members.

Claims 119 and 128: Bolanos discloses the claimed device except for the tube including a port for an endoscope at its proximal end.

Stevens et al. teaches an endoscope being inserted into the proximal end of an elongated tube at a port 90, in order for there to be visualization, and it is known in the art that incorporating endoscopes with surgical instruments allows for less invasive surgery by having the surgeon view the surgical site via the endoscope (col. 21, lines 63-67). It would have been obvious to one of ordinary skill in the art to provide an endoscope port at the proximal end of an elongated tube, as taught by Stevens et al., to Bolanos in order to allow for visibility during fundoplication.

Response to Arguments

8. Applicant's arguments with respect to Claims 110, 117, 120-122, 124-127, 129, 130, 135 have been considered but are moot in view of the new ground(s) of rejection, necessitated by Applicant's amendment.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER